



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and commercialization of engineered cell therapies for the treatment of cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this Notice to Affini-T Therapeutics, Inc. (“Affini-T”), headquartered in Watertown, MA.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute’s Technology Transfer Center on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Andrew Burke, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center, Telephone: (240)-276-5484; E-mail: andy.burke@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. United States Provisional Patent Application No. 63/185,805 filed May 7, 2021, entitled “T Cell Receptors Recognizing C135Y, R175H or M237I Mutation in P53” [HHS Reference No. E-101-2021-0-US-01]; and

2. PCT Application No. PCT/US2022/028066 filed May 6, 2022, entitled “T Cell Receptors Recognizing C135Y, R175H or M237I Mutation in P53” [HHS Reference No. E-101-2021-0-PCT-02].

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to the following:

“Development, manufacture and commercialization of T or Natural Killer cell therapy products genetically engineered to express the P53 R175H-reactive T cell receptor claimed in the Licensed Patent Rights for the treatment of cancer in humans.”

E-101-2021 patent family is primarily directed to isolated TCRs reactive to certain mutated forms of tumor protein 53 (TP53 or P53), within the context of several human leukocyte antigens. *P53* is the archetypal tumor suppressor gene and the most frequently mutated gene in cancer. Contemporary estimates suggest that >50% of all tumors carry mutations in *P53*. Because of its prevalence in cancer and its restricted expression to precancerous and cancerous cells, this antigen may be targeted on mutant P53-expressing tumors with minimal normal tissue toxicity.

This Notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published Notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information from these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 USC 552.

Dated December 22, 2022.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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